MEDTECH INSIGHT
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News We're Watching: Abbott, Click, Otsuka, Prenosis Win FDA Approval; EU Health Data Space Proposal, And More

by Marion Webb

This week, Abbott, Click and Otsuka, Prenosis won the FDA nod respectively for an in vitro diagnostic to evaluate patients for concussion, the first prescription digital therapeutic to treat major depressive disorder and a software to predict sepsis. Also on the regulatory front, the FDA will now take 513(g)s forms via its eSTAR framework. In Europe, the debate of what personal information can be shared continues.

FDA Seeks Industry Representative For GMP Committee

The FDA needs a new industry voice for its quality systems advisory panel, the agency said in a 5 April Federal Register Announcement.

The notice makes two requests. First, the agency is asking for written statements of interest from industry groups interested in helping to select a nonvoting industry representative for the Device Good Manufacturing Practice Advisory Committee (DGMPAC). The US Food and Drug Administration also wants nominations for individuals who could serve as the representative, which may be self-selected or submitted by an organization.

Interested individuals or groups are being asked to contact the FDA by 6 May. Organizations interested in participating in the selection process should contact Margaret Ames at *Margaret.Ames@fda.hhs.gov*, while representative nominations may be submitted through the *FDA's Advisory Committee Membership Nomination Portal*.

Biolinq Raised $58M In Financing To Support Clinical Trial

Biolinq Incorporated , which developed a wearable patch for measuring glucose levels, announced on 4 April it completed $58m in financing, led by Alpha Wave Ventures with participation from Niterra's corporate venture capital fund. The company will use the funding to conduct a pivotal

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trial in the US this year to evaluate the efficacy of the proprietary intradermal glucose sensor to support subsequent FDA submission.

Abbott Wins Clearance For Concussion Test

The FDA has cleared *Abbott* 's *510(k) Premarket Notification (fda.gov)*, an vitro diagnostic to help evaluate patients with mild traumatic brain injury (mTBI) — commonly referred to as concussion — at the point of care or in clinical laboratory settings within 24 hours of injury.

The purpose of the i-STAT TBI cartridge is to assist clinicians in determining if the patient needs a CT scan of the head. (Also see "*Abbott Gains FDA Clearance For Lab-Based Concussion Test*" - Medtech Insight, 7 Mar, 2023.)

Abbott said the test can produce "lab-quality" results in 15 minutes. It works by measuring levels of glial fibrillary acidic protein and ubiquitin carboxyl-terminal hydrolase L1 protein in whole blood using the i-STAT Alinity instrument.

Previous tests to evaluate TBI, according to Abbott, were only cleared for use with plasma or serum, requiring samples to be sent to a lab for processing and testing. Nearly 5 million people go to the emergency room every year for brain injuries, according to the National Institutes of Health. However, half of those who suspect having sustained a concussion, never go to the ER or have it checked out by a medical professional.

Will The European Health Data Space Deliver Value To Medtech?

The Council of the EU and the European Parliament reached a provisional agreement on the proposed European Health Data Space Regulation on March 18.

The EHDS will collect and store patient data, e.g., electronic health records, for primary and secondary purposes. Third-party organizations, e.g., pharmaceutical companies, will be granted access to huge amounts of EU patient data through the data space's secondary-purpose.

The provisional agreement still needs to be endorsed by the Council of the EU and the Parliament before being formally adopted by both institutions. The regulation become enforced 20 days after publication in the EU's Official Journal.

Despite this, industry, including trade body organizations such as MedTech Europe and COCIR, have continued to voice "deep concerns" over the proposed regulation and called for the regulation to "better serve" its intended purpose.

One concern raised by trade bodies was the potential for legal fragmentation at a national level.

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As it stands, the EHDS regulation permits member states to decide whether patients can opt out of their data being accessed for primary or secondary purposes.

Patient opt-out was previously a point of contention between the European Parliament and the Council of the EU during trilogues negotiations.

If the data isn't representative and of high quality, the EHDS may not deliver on its primary benefit to the medtech industry.

The primary purpose of the EHDS is to provide a fluid data network that will allow EU citizens to access health care anywhere in the EU. This will be accessible by the MyHealth@EU platform. For example, a German citizen could have their prescription dispensed in a Spanish pharmacy, while traveling.

The secondary purpose allows third party groups to access patient data that has been anonymized or pseudonymized for research, policy making and regulatory activities, for example. Data for secondary purposes is accessible by the HealthData@EU, currently in its pilot phase.

First Pharma Companies Receive FDA Approval For PDTx To Treat Depression

Otsuka America Inc. and *Click Therapeutics, Inc.* have received *FDA clearance* for Rejoyn, the first prescription digital therapeutic smartphone app for treating major depressive disorder (MDD).

The digital therapeutic is intended to be used as an "adjunct" to outpatient care and antidepressant medication, according to Otkuska.

It will be available on the Android and iPhone app store in the latter half of 2024. The FDA described the app as providing interactive cognitive-emotional and behavioral therapeutic intervention, including Emotional Faces Memory Tasks (EFMT), cognitive behavioral therapy-based lessons, and text messaging to the patient to reinforce lessons content and to encourage use of the app. (Also see "*Click Therapeutics And Indivior Collaborate On Prescription Digital Therapeutics In Substance Use Disorder*" - Medtech Insight, 7 Sep, 2023.)

EFMT is *a brain training exercise* developed by Click Therapeutics. It works to balance brain activity in the amygdala and prefrontal cortex by identifying emotions on a series of faces, thus decreasing MDD symptoms.

While digital therapeutics have shown promising, reimbursement remains tricky. *Pear Therapeutics, Inc.* had both public and private insurance coverage, but the company still filed for Chapter 11 bankruptcy in June 2023. (Also see "*'It's Not Going To Happen Overnight': Payors On*

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Pear Fallout And Digital Therapeutic Coverage Prospects" - Medtech Insight, 23 Jun, 2023.)

Recently, a report from the Peterson Health Technology Institute found that digital therapeutics for diabetes management showed "minimal" and "short-term" clinical benefits. (Also see "*Report Finds Digital Diabetes Tools Deliver No 'Meaningful Clinical Benefits'*" - Medtech Insight, 27 Mar, 2024.) The same digital therapeutics didn't show improved health equity and access to care, either.

FDA Authorizes AI Sepsis Tool Via De Novo Pathway

Prenosis received FDA clearance for its Sepsis ImmunoScore, an AI/ML software as a medical device (SaMD) intended to guide rapid diagnosis and prediction of sepsis, a complex and potentially life-threatening condition that can be difficult to diagnose.

The tool works by leveraging a combination of biomarkers and clinical data through AI technology. The ImmunoScore, according to Prenosis, aids in evaluating the risk of a patient developing sepsis within 24 hours of entering the hospital.

The tool can further assess a patient's risk of deterioration "represented by length of stay in the hospital, in-hospital mortality, and escalation of care within 24 hours (ICU admission, mechanical ventilation placement, and/or vasopressor use)," the company said.

The combination of both diagnostic and predictive information has never been previously available in a legally marketed device for sepsis, Prenosis said.

GE HealthCare Adds AI Power To Handheld Ultrasound Device

GE HealthCare Technologies, Inc. announced on 3 April it launched its Caption AI software on its Vscan Air SL handheld ultrasound device for early detection of heart disease.

Clinicians can use the device for real-time, step-by-step guidance to capture diagnostic-quality images and automated ejection fraction estimation to help them make clinical decisions in cardiac care, GE HealthCare said. The Vscan Air SL will make its debut at the 2024 American College of Cardiology (ACC) annual scientific meeting, held from 6-8 April in Atlanta.

Vscan aims to capture cardiac images so even non-expert ultrasound users can take a quick look at patients' hearts.

"With the increase of cardiovascular disease and shortage of sonographers around the globe, innovations like the Vscan Air SL with Caption AI are hugely transformative in cardiac care, supporting rapid and confident assessments at the point of care," said cardiologist Jordan Strom.

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"AI guidance has enormous potential in ultrasound due to its ability to guide experts and relatively new users in retrieving diagnostic-quality information to make timely and accurate decisions and get patients on the right path sooner."

FDA Now Taking 513(g)s Via eSTAR

Manufacturers seeking clarification on a product's likely FDA regulatory classification can now submit a 513(g) request for information through the eSTAR portal, the FDA announced recently.

The announcement makes 513(g)s the first non-submission form to use the eSTAR framework. The portal, which walks manufacturers through completing regulatory forms, became mandatory for 510(k) submissions in October 2023 and is now optional for PMAs.
Medtech Insight spoke to regulatory specialists about the practicalities of using the portal in January. (Also see "*The Practicalities Of Working With The FDA's eSTAR Submission Form*" - Medtech Insight, 8 Feb, 2024.)

Dental Bone Graft Guidance Doc Issued

A new *draft guidance document* from the FDA details the agency's preferred approach to animal testing for materials used in dental bone grafts.

The document is intended for developers of 510(k) dental bone graft material devices, which may require some animal testing to meet the FDA's special controls. Devices covered by the document may be made from materials including hydroxyapatite, tricalcium phosphate, polylactic and polyglycolic acids, and collagen.

The FDA recommends manufacturers use canine or porcine models rather than rodent models because "the dental anatomy of dogs and pigs more closely resemble human dentoalveolar architecture than that of smaller animals." Additionally, the models should replicate the worst-case scenario for intended use. Cranial and orthopedic models are usually not sufficient for dental devices, the agency says.
Comments on the draft are open at regulations.gov under *docket no. FDA-2024-D-1242* until 28 May.

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